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09/543,264	04/05/2000	Benjamin D. Pless	459992000700	6469

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EXAMINER

BRADFORD, RODERICK D

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/543,264

Applicant(s)

PLESS, BENJAMIN D.

Examiner

Roderick Bradford

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 23-40 and 62-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-22, 41-53 and 58-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of restriction in Paper No. 7 is acknowledged. The traversal is on the ground(s) that because each group would be found in the same subclass that additional proof beyond "notoriety" of "separate" status is required. This is not found persuasive because proof of "notoriety" of "separate" status has been made in Paper No. 7 by showing that the subcombinations are distinct and can be used separately. In addition, the inventions have acquired a separate status in the art because of their "recognized divergent subject matter".

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's election with traverse of election of species in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the basis for the election of species requirement has not been established. This is not found persuasive because applicant has not submitted evidence or identified such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In addition, the different species represent the different ways the pulse parameters can be used.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 23-40 and 66-81 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected method for treating neurological conditions by using at least one burst to detect electrically activity, by the use of electrodes, and by using hyperpolarizing pulse, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

### ***Drawings***

4. Figures 1A-5A should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 1, "which" is vague since it fails to particular point out.

Referring to claim 3, "detected" is in the passive voice and steps for a method should be in the active voice. In addition, the claim needs to set forth that electrical activity is being detected. "Electrical activity" lacks antecedent basis.

Referring to claims 4 and 5, "said detected electrical activity" lacks antecedent basis.

Referring to claim 6, "selected" is in the passive voice and steps for a method should be in the active voice.

Claims 9-14, are written in the passive voice and steps for a method should be in the active voice.

Referring to claim 15, "said at least one electrical pulse" lacks antecedent basis.

Referring to claim 18, "said electrical signal" lacks antecedent basis

Referring to claim 19, "related" and "detected" are in the passive voice and steps for a method should be in the active voice. "Said detected electrical signal" lacks antecedent basis.

Referring to claim 21, "said detected epileptiform pulse-to-pulse interval" lacks antecedent basis.

Claim 22 is written in the passive voice and steps for a method should be in the active voice.

Referring to claim 41, "electrical signal" lacks antecedent basis.

Referring to claim 42, "electrical signal" lacks antecedent basis. "Again detecting" is vague since no step has been set forth for first detecting for it to be "again"

Referring to claim 43, "said re-analyzed" lacks antecedent basis. "Shows" is vague since no step has been set forth for to "show".

Referring to claim 46, is claim 46 in addition to claim 1's applying steps.

Referring to claims 47 and 48, are written in the passive voice and steps for a method should be in the active voice.

Referring to claim 49, "said electrical signal" lacks antecedent basis.

Referring to claims 57 and 58, "a first brain electrical activity sensor" lacks antecedent basis.

Referring to claim 60, "to said brain" is inferentially included and needs to be positively recited.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-8, 12-14, 18, 19, 50-53, 57, 58, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. U.S. Patent No. 5,713,923.

Referring to claim 1, Ward discloses a method for treating abnormal neurological condition comprising the steps of applying to brain tissue at least one electrical burst comprising a multiplicity of pulses (column 9, line 29), said pulses having pulse parameters (column 9, lines 12,13), at least one of which pulse parameters vary during the burst (column 9, lines 28-32).

Referring to claim 2, wherein at least two pulse parameters vary during the burst (column 9, lines 28-32).

Referring to claim 3, wherein said burst is synchronized to detect electrical activity of the brain (Table IV).

Referring to claim 4, wherein said electrical activity is an epileptiform electrical activity (column 5, lines 3 and 4).

Referring to claim 5, wherein said electrical activity predicts impending epileptiform electrical activity (column 5, lines 3 and 4).

Referring to claim 6, wherein said pulse parameters are selected from the group consisting of selected electrodes, pulse width, pulse amplitude, pulse polarity, and pulse-to-pulse interval (column 9, lines 28-32).

Referring to claim 7, wherein at least one pulse parameter is pulse-to-pulse interval (column 9, lines 12-14).

Referring to claim 8, wherein said pulse-to-pulse interval is between about 3 and 300 microseconds (column 9, line 33).

Referring to claim 12, wherein said pulse-to-pulse interval is incrementally increased (column 8, lines 49-54).

Referring to claim 13, wherein said pulse-to-pulse interval is incrementally decreased (Table IV).

Referring to claim 18, wherein method further includes the step of detecting said electrical signal prior to initiating the application of said at least one electrical burst (column 5, lines 3-6).

Referring to claim 19, wherein said at least one pulse parameter is related to said detected electrical signal (column 9, lines 19-21).

Referring to claim 50, at least a first electrical electrode (column 5, lines 12 and 13), and at least an electrical signal source, said first electrical signal source initiating a stimulation burst to said electrode, said burst having pulse parameters (column 9, lines 12,13), which the pulse parameters vary during said burst (column 9, lines 28-32).

Referring to claim 52, wherein said electrical signal source is configured to vary pulse parameters selected from the group consisting of electrode choice, pulse width,

pulse amplitude, pulse polarity, and applied pulse-to-pulse interval (column 9, lines 28-32).

Referring to claim 53, wherein the first electrical signal source is configured to vary said pulse parameters randomly, pseudo-randomly, fractally, incrementally increasing and decreasing, or effectively to avoid initiation of epileptiform activity (column 8, lines 49-54).

Referring to claim 57, wherein said at least a first brain electrical activity sensor is configured to detect epileptiform activity prior to initiating the application (column 5, lines 3-6).

9. Claims 50, 52, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Weijand et al. U.S. Patent No. 5,792,212.

Referring to claims 50, Weijand discloses an assembly with at least a first electrical electrode (31, 32), and at least an electrical signal source (30), said first electrical signal source initiating a stimulation burst to said electrode (column 4, lines 27 and 28), said burst having pulse parameters (column 2, lines 43-45), which the pulse parameters vary during said burst (column 4, lines 4 and 5).

Referring to claim 52, wherein said electrical signal source is configured to vary pulse parameters selected from the group consisting of electrode choice, pulse width, pulse amplitude, pulse polarity, and applied pulse-to-pulse interval (column 5, lines 22-25).

Referring to claim 53, wherein the first electrical signal source is configured to vary said pulse parameters randomly, pseudo-randomly, fractally, incrementally

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increasing and decreasing, or effectively to avoid initiation of epileptiform activity  
(column 7, lines 33-35).

***Allowable Subject Matter***

13. Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*R. Bradford*

4/22/02

R.B.

April 22, 2002

*u u*  
**GEORGE R. EVANISKO**  
**PRIMARY EXAMINER**

4/22/02

**Attachment for PTO-948 (Rev. 03/01, or earlier)**  
**6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

**Failure to take corrective action within the set period will result in ABANDONMENT of the application.**